UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PATRICIA HAUGHTON	)	
	)	
	)	
PLAINTIFF	)	
	)	
V.	)	
	)	C.A. No. 11217 RGS
HILL LABORATORIES, INC.	)	
	)	
	)	
DEFENDANT	)	

HILL LABORATORIES, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

The defendant, Hill Laboratories, Inc. ("Hill Laboratories") has moved pursuant to Fed. R. Civ. P. 56 for entry of an Order granting summary judgment in its favor on all claims (Counts I through IV) asserted in the Plaintiff's Amended Complaint. Summary judgment is appropriate because the plaintiff cannot establish a prima facie case as to any theory of recovery alleged: (1) as to Count I alleging negligent failure to warn, she has no evidence to prove that Hill Laboratories failed properly to warn her physicians (or her) with regard to the product Tri-Luma Cream or that such failure to warn was the proximate cause of her alleged injuries, and moreover, these claims are preempted by federal law; (2) as to Count II alleging breach of implied warranty of merchantability, the plaintiff has no evidence to prove the existence of a defect in the Tri-Luma Cream that she claims to have used, much less, that any alleged defect proximately caused her injuries; (3) as to Count III alleging breach of the implied warranty of fitness for a particular purpose, the plaintiff has no evidence to prove that she made known to Hill

Laboratories that she purchased Tri-Luma Cream for a specific use and that Hill Laboratories supplied the drug to her for this specific use, distinct from its general usage; and (4) as to Count IV alleging intentional infliction of emotional distress, the plaintiff has no evidence to establish extreme and outrageous conduct by Hill Laboratories that resulted in severe distress to the plaintiff. It should be noted that the plaintiff has elected to proceed without an expert; and therefore, she is incapable as a matter of law of proving any defect in Tri-Luma Cream or medical causation for the injuries that she alleges arose out of her use of Tri-Luma Cream.

CONCISE STATEMENT OF MATERIAL FACTS AS TO WHICH THERE IS NO ISSUE TO BE TRIED

Pursuant to Local Rule 56.1, Hill Laboratories, Inc.'s states that the following is a concise statement of the material facts of record as to which it contends there is no issue to be tried.

1. Plaintiff asserts in her Amended Complaint and Demand for Jury Trial ("Amended Complaint"), that in March of 2003 she was seen by Katheryn Bowers, M.D. at Dermatology Associates of Concord, Inc. Exhibit 1, Amended Complaint and Demand for Jury Trial, Paragraph 3.

2. The plaintiff revealed in her deposition that she suffered from pigmentation changes in certain areas of her body. Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume II, Page 38, Line 1-10.

3. She alleges that in March of 2003, Dr. Bowers gave her a prescription for Tri-Luma Cream. Exhibit 1, Amended Complaint and Demand for Jury Trial, Paragraphs 3, 4.

4. The plaintiff subsequently had the prescription filled and applied the Tri-Luma Cream to her face. Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume II, Page 66, Lines 6-8, Page 78, Lines 11-14.

5. The plaintiff did not read the written information, instructions and warnings provided with the Tri-Luma Cream before she applied the cream to her face. Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume II, Page 70, Lines 18-22, and Page 71, Lines 17-21.

6. As of the date of her deposition, the plaintiff did not know what company manufactured Tri-Luma Cream, and she has never made a claim that she interacted with Hill Laboratories with regard to the purchase or application of Tri-Luma Cream. Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume II, Page 197, Lines 2-24.

7. The plaintiff cannot recall such details as the number of applications she made of the Tri-Luma Cream to her face. Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume II, Page 167, Lines 3-7.

8. She alleges, however, that at some point after the she applied Tri-Luma Cream to her face, she woke up in the morning with red marks on her cheeks. Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume II, Page 80, Line 24, Page 81, Line 3.

9. The plaintiff initially brought suit on October 14, 2004 against her physicians, Kathryn Bowers, M.D. and Merill G. Liteplo, M.D., alleging personal injuries arising out of her prescribed use of Tri-Luma Cream. Exhibit 3, Complaint and Demand for Jury Trial in Patricia Haughton v. Kathryn Bowers, M.D. and Merill Liteplo, M.D., Middlesex Superior Court, C.A. No. 04-4017.

10. The Plaintiff's claims against Kathryn Bowers, M.D. and Merill G. Liteplo, M.D. were dismissed with prejudice on April 7, 2006 for failure to file a bond. Exhibit 4, Amended Judgment.

11. The Plaintiff filed the present action against Hill Laboratories on March 24, 2006 and subsequently filed an Amended Complaint in this action on June 20, 2006. Exhibit 1, Amended Complaint and Demand for Jury Trial.

12. The plaintiff's description of her claims of defect and failure to warn in this case are vague and conclusory. In responding to interrogatories asking her to "[d]escribe each and every alleged defect in Tri-Luma that caused [her] injuries," the plaintiff responded simply that "[t]he product did not work as intended, nor did it forewarn [her] that it was defective and would result in unfavorable, permanent side effects. Due to insufficient warnings and consequences associated with the medication, [she] has suffered permanent disfigurement and scarring." Exhibit 5, Plaintiff's Response to Defendant, Hill Laboratories Interrogatories, Response No. 9.

13. The plaintiff provided an equally vague response to an interrogatory requesting her to "state each and every way in which the information provided with Tri-Luma was inadequate and [to] set forth with specificity what warnings or instructions should have been provided," answering only that "[t]he Defendant neglected to properly inform [her] and all consumers of the detrimental side effects and disfigurement that would occur by using said product," and "[f]ailure to provide adequate warnings, precautions and/or instructions resulted in the injuries suffered by the Plaintiff." Exhibit 5, Plaintiff's Response to Defendant Hill Laboratories Interrogatories, Response No. 14.

14. Further, the plaintiff has not shown how any additional warnings provided with the Tri-Luma Cream would have made any difference given that she never read any of the instructional materials or warnings that came with the cream. Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume 2, Page 70, Lines 18-22, and Page 71, Lines 17-21.

15. Hill Laboratories manufactures a dermatological product known as Tri-Luma® Cream ("Tri-Luma Cream"). Exhibit 6, Affidavit of Ronald Gottschalk, MD, FRCPC, Paragraph 6.

16. Tri-Luma Cream is a Food and Drug Administration (FDA) approved drug, manufactured in compliance with the requirements of the Current Good Manufacturing Practice as defined in 21 CFR parts 210 and 211. Exhibit 6, Affidavit of Ronald Gottschalk, MD, FRCPC, Paragraph 6.

17. The active ingredients of Tri-Luma Cream are fluocinolone acetonide 0.01%, hydroquinone 4% and tretinoin 0.05%. Exhibit 6, Affidavit of Ronald Gottschalk, MD, FRCPC, Paragraph 6.

18. The label for Tri-Luma Cream contains the information required by the Federal Food Drug and Cosmetic Act and its implementing regulations. Exhibit 7, Affidavit of Paul M. Clark, Paragraph 16.

19. Specifically, the Tri-Luma Cream label includes a description of the product and information pertaining to: clinical pharmacology, indications and usage, contraindications, warnings, precautions, adverse reactions, drug abuse dependence, overdosage, dosage and administration and how the product is supplied. Exhibit 7,

Affidavit of Paul M. Clark, at Paragraphs 12 and 17; see also Tri-Luma Cream labeling and package inserts attached to Exhibit 7 as Exhibit B, Affidavit of Paul M. Clark.

20. This type of product labeling is required by the FDA as part of the approval process for any New Drug Application. Exhibit 7, Affidavit of Paul M. Clark Paragraph 14.

21. If the FDA determines that a new drug applicant's labeling is insufficient, the FDA will not approve the drug for marketing. Exhibit 7, Affidavit of Paul M. Clark Paragraph 14.

22. The labeling for Tri-Luma Cream has been approved by the FDA. Exhibit 7, Affidavit of Paul M. Clark Paragraph 15.

23. Tri-Luma Cream is indicated for the short-term intermittent treatment of moderate to severe melasma of the face, in the presence of sun avoidance, including the use of sunscreens. Exhibit 6, Affidavit of Ronald Gottschalk, Paragraph 8.

24. Melasma is a disorder of hyperpigmentation of the skin seen more commonly on the face of females. Exhibit 6, Affidavit of Ronald Gottschalk at Paragraph 9.

SUMMARY JUDGMENT STANDARD

Even when viewing all of the evidence in the light most favorable to the plaintiff, she cannot make a showing of negligent failure to warn, breach of the implied warranty of merchantability, breach of the implied warranty of fitness for a particular purpose or intentional infliction of emotional distress in this action. As there is no genuine issue as to any material facts, this Court should grant Hill Laboratories' Motion for Summary Judgment.

Federal Rule of Civil Procedure 56(b) provides that "a party against whom a claim...is asserted...may, at any time, move with or without supporting affidavits, if any, showing that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

> [T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be no "genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other fact immaterial.
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> Of course, a party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of "the pleadings, depositions, answers, and admissions on file, together with the affidavits, if any," which it believes demonstrate the absence of a genuine issue of material fact.
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> [But] the burden on the moving party may be discharged by "showing"--that is, pointing out to the district court -- that there is an absence of evidence to support the nonmoving party's case.

Celotex corp. v. Catrett, 477 U.S. 317, 322-323, 325 (1986). Once such a showing has been made, the burden shifts to the party opposing summary judgment to come forward with specific, concrete, admissible evidence sufficient to prove every element of his claim at trial. Conclusory allegations, improbable inferences, unsupported speculation, hearsay, and incompetent opinions are not enough. Fed. R. Civ. P. 56(e); Hayes v. Douglas Dynamics, Inc., 8 F.3d 88, 92 (1st Cir. 1993); Leblanc v. Great American Ins. Co., 6 F.3d 836, 841-42 (1st Cir. 1993); Federal Deposit Insurance Corp. v. Fonseca, 795 F.2d 1102, 1110 (1st Cir. 1986).

ARGUMENT

I. The Plaintiff's Negligent Failure to Warn Claims Fail.

A. The Plaintiff Has Insufficient Evidence to Establish a Failure to Warn

Summary Judgment should be entered on Count I of the plaintiff's Amended Complaint because she has insufficient evidence to establish that Hill Laboratories failed to warn of a non-obvious risk associated with the normal use of Tri-Luma Cream about which it knew or should have known. Garside v. Osco Drug, Inc., 976 F.2d 77, 81 (1st Cir. 1992)(applying Massachusetts law); Knowlton v. Deseret Medical, In., 930 F.2d 116, 119-120 (1st Cir. 1991)(applying Massachusetts law); MacDonald v. Ortho Pharmaceutical Corp., 394 Mass. 131 (1985). Massachusetts courts have followed the settled law that a manufacturer's duty to warn of risks associated with the use of prescription drugs extends to the prescribing physician rather than to the patient. Garside, 976 F.2d at 80; Knowlton, 930 F.2d at 120 n. 2; McDonald, 394 Mass. at 136-138 (distinguishing the duty to warn related to the risks of oral contraceptives as compared to other ethical drugs). The rationale underlying this rule is that the prescribing physician is the learned intermediary whose role it is to stand between the manufacturer and the patient. Garside, 976 F.2d at 80. As the learned intermediary, the prescribing physician is in the best position to evaluate the risks and benefits associated with the use of a particular drug and can thereafter advise the patient accordingly. Id. "Under this doctrine, the manufacturer's duty is fulfilled once it adequately warns the physician." Id.

Under the circumstances of this case, the plaintiff cannot establish her claim that Hill Laboratories failed properly to warn her prescribing physician of the risks associated with Tri-Luma Cream. The plaintiff has never articulated the precise risks associated with her use of Tri-Luma Cream about which Hill Laboratories failed to warn. See Exhibit 5, Plaintiff's Response to Defendant, Hill Laboratories Interrogatories, Response No. 14. The undisputed facts establish that information in the nature of FDA approved warnings and instructions accompany Tri-Luma Cream as it is distributed. Exhibit 7, Affidavit of Paul M. Clark, Paragraphs 16-17 and Exhibit B to the affidavit. The plaintiff has never argued, much less, presented evidence that the instructions and warnings provided with Tri-Luma Cream were not adequate to put the average dermatologist on notice of the risks involved in the use of Tri-Luma Cream. See Lareau v. Page, 840 F.Supp. 920, 931 (D. Mass. 1993)(applying Massachusetts law). Moreover, the plaintiff has no evidence to suggest that her prescribing physician was unaware of the risks associated with the use of Tri-Luma Cream or that her conduct would have been effected by other instructions and warnings. Id. at 932-933.

In addition, any suggestion by the plaintiff that she was not informed of the risks of Tri-Luma Cream should be disregarded as irrelevant as she never read the instructions, warnings and other written information that accompanied her prescription of Tri-Luma Cream, Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume 2, Page 70, Lines 18-22, and Page 71, Lines 17-21. Therefore, the alleged "inadequate warnings" could not be the cause in fact of any of her purported injuries. Wasylow v. Glock, Inc., 975 F.Supp. 370, 378 (D. Mass 1996)("as with all negligence actions, failure to warn will not constitute negligence if it is not a proximate cause of the plaintiff's injuries").

B. The Plaintiff's Failure to Warn Claim is Preempted by the Food Drug and Cosmetic Act

The plaintiff's failure to warn claim essentially argues that Hill Laboratories is liable for failing to provide warnings that were not required by the FDA at the applicable time. Failure to warn claims of this type conflict with the FDA's exercise of its statutory obligation to obtain a proper balance of public health considerations in the context of the labeling of prescription drugs. Accordingly, such claims are preempted by the FDA regulatory scheme. For this reason, Hill Laboratories is entitled to summary judgment on this claim.

Under the Supremacy Clause of the United States Constitution, preemption of state law occurs when a state law liability standard conflicts with federal law by standing as an obstacle to federal objectives. See Crosby v. National Foreign Trade Council, 530 U.S. 363, 372 (2000). Implied conflict preemption serves to prevent state law legal principles that would conflict with the federal regulatory scheme, as enforcement of state law principles in such circumstances "would take from those who would enforce a federal law the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary preemption principles, seeks to protect." Geier v. American Honda Motor Co., 529 U.S. 861, 871-72 (2000). Because the plaintiff's claims would conflict with the ability of the FDA to accomplish its purposes under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. section 355(a), they are preempted.

In the January 2006 Preamble to its Final Rule regarding prescription drug labeling, the FDA stated its position that "FDA approval of labeling under the [FDCA], whether it be in the old or new format, preempts conflicting or contrary state law." Exhibit 8, 71 Fed. Reg. 3922, 3934. The rationale for its position was stated as follows:

> If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness (sic) information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted.

71 Fed. Reg. at 3969.

Courts increasingly are giving deference to the FDA's interpretation of the preemptive effect of its regulations and have held that state law failure to warn claims involving prescription drugs are preempted.[1] See Sykes v. Glaxo-Smithkline, 484 F.Supp.2d 289 (E.D. Pa. 2007)(plaintiff's failure to warn claims preempted); In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation, 2006 WL 2374742 (N.D. Cal)(failure to warn claims preempted because they conflict with the FDA's determination of what warnings are substantiated by the scientific evidence); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006)(analyzing 2006 Preamble and finding product liability claims preempted); Abramowitz v. Cephalon, Inc., 2006 WL 560639, at *3 (N.J. Super. Mar 3, 2006)("It is clear that FDA has assumed authority over the regulation and approval of pharmaceutical labels in the United States, and therefore,

[1] The defendant recognizes that there are courts that have addressed this issue both prior to and following the publication of the January 2006 Preamble which have declined to find state law failure to warn claims preempted. See e.g. Sullivan v. Wyeth fka American Home Products Corp., 2007 WL 1302589 (Mass.Super.)(after analyzing the 2006 preamble declined to find preemption of state law claims). See also Gurski v. Wyeth Ayerst Divison of American Home Products Corporation, 953 F.Supp. 412 (D. Mass.) 1997)(in which the court did not directly address preemption but noted that compliance with federal regulations is not dispositive but it is evidence going to the warning's adequacy); Colacicco v. Apotex, Inc., 432 F.Supp.2d 514, 535 (E.D. Pa. 2006) (citing to various state cases which have decided that state failure to warn claims are not preempted).

any state claim that would challenge an FDA approved warning is preempted"). See also Conte v. Wyeth, Inc., 2006 WL 2692469 (Cal. Superior)(following the reasoning in the court's decision in In re Bextra, supra, the court found state law warnings claims preempted). This Court should do the same.

II. The Plaintiff's Breach of Implied Warranty Claims Fail.

Hill Laboratories is entitled to summary judgment on Count II of the plaintiff's Amended Complaint alleging a breach of the implied warranty of merchantability because the plaintiff has no evidence to establish the existence of a defect or an unreasonably dangerous condition in the Tri-Luma Cream. Colter v. Barber-Greene Co., 403 Mass. 50, 62 (1988). Notably, the plaintiff has never identified with any degree of particularity a defect in the formulation of the product; and therefore, at this stage of the litigation, it should be assumed that she is not making that claim. See Sprague v. Upjohn Company, 1995 WL 376934 (D. Mass)(applying Massachusetts law), citing Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 655)(1st Cir. 1981)(design claim alleged another formulation of the oral contraceptive at issue would have been equally effective but safer). Moreover, the plaintiff has never claimed that Tri-Luma Cream should never have been designed or manufactured at all. See Sprague, supra, (discussing the role of the FDA rather than the courts or juries to determine whether a prescription drug should be approved and marketed).

The plaintiff's vague allegations of defect simply state only that "[t]he product did not work as intended." See Exhibit 5, Plaintiff's Response to Defendant Hill Laboratories

Interrogatories, Response No. 9.[2] She makes this claim without stating what the cream was intended to do and how it, in her view, fell short.

Importantly, the plaintiff does not support her nebulous allegations of a defect or a dangerous condition in Tri-Luma Cream with any testimony by an expert, and in the circumstances here involving a prescription drug, the failure to support her claims with an expert is fatal. The courts in Massachusetts have made clear, that in cases such as this, involving claims of defect necessarily raising highly technical and specialized questions not within the knowledge of ordinary lay jurors, expert testimony on the subject of defect is required. Gofredo v. Mercedes-Benz Truck Co., Inc., 402 Mass. 97, 103-104 (1988); Morrell, 36 Mass. App. Ct. at 936; Gynan v. Jeep Corp., 13 Mass. App. Ct. 504, 508 (1982); Wiska v. St. Stanislaus Social Club, Inc., 7 Mass. App. Ct. 813, 820-21 (1979). See also Doe v. Solvay Pharmaceuticals, Inc., 153 Fed.Appx. 1, 3 (1st Cir. 2005)(applying Maine law)(holding that expert testimony was required to support claims against drug manufacturer after "severe manic reaction" to prescription drug, where state law required expert testimony with regard to issues not within the common knowledge of lay jurors). Having failed to meet her burden to show that Tri-Luma Cream was in any way defective, unreasonably dangerous or unfit for the ordinary purposes for which it was to be used, Lubanski v. Coleco Indus., Inc., 929 F.2d 42, 48 (1st Cir. 1991)(applying Massachusetts law); Kearny v. Philip Morris, Inc., 916 F. Supp. 61, 64 (D. Mass. 1996)(applying Massachusetts law), plaintiff may not proceed on her breach of implied warranty of merchantability claim.

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[2] The plaintiff also alleges vaguely that Hill Laboratories did not "forewarn [her] that [Tri-Luma] was defective and would result in unfavorable, permanent side effects." See Exhibit 5, Plaintiff's Response to Defendant, Hill Laboratories Interrogatories, Response No. 9. These claims are addressed in Section I supra.

Moreover, without an expert, the plaintiff cannot meet her burden to show that the injuries and damages complained of were proximately caused by a defect in Tri-Luma Cream. It is well settled in Massachusetts that "[b]ecause understanding medical causation is 'beyond the ... knowledge of the ordinary layman ... proof of it must rest upon expert medical testimony.'" Theresa Canavan's Case, 432 Mass. 304, 316 (2000) (quoting Hachadourian's Case, 340 Mass. 81, 85 (1959). It is not enough for the plaintiff to introduce her own testimony that following her use of Tri-Luma Cream, she developed her alleged skin injury. Enrich v. Windmere corp., 416 Mass. 83, 87 (1993)(the opinion testimony of non-experts cannot substitute for expert testimony).

In sum, it would be improper to allow the plaintiff to pursue a claim of breach of the implied warranty of merchantability when she makes vague allegations of defect and medical causation, which are unsupported by expert testimony. Summary judgment should appropriately be granted in favor of Hill Laboratories.

III. The Plaintiff's Breach of Warranty of Fitness for a Particular Purpose Claim Fails

Summary judgment should be entered in favor of Hill Laboratories on Count III of the Amended Complaint alleging a breach of the implied warranty of fitness for a particular purpose. An implied warranty of fitness for a particular purpose will exist only where at the time of contracting, the seller has reason to know of a particular purpose for which the goods are required and the buyer relies on the seller's skill or judgment to select or furnish suitable goods. G.L. c. 106, section 2-315. Fernandes v. Union Bookbinding, 400 Mass. 27, 33-36 (1987). In the present case, the plaintiff can not prove her more general breach of implied warranty claim, much less the elements of her narrower claim for breach of implied warranty of fitness for a particular purpose.

As set forth in Sections I and II supra, the plaintiff cannot establish the elements of either her negligent failure to warn or breach of implied warranty claims. When the plaintiff cannot prove a breach of implied warranty claim, that is to say, that a product is defective or unfit for its intended purpose, then as a matter of law, she cannot prove the more narrow claim of breach of the implied warranty of fitness for a particular purpose. Scialdone v. National Crane Corp., 53 Mass. App. Ct. 1108, *5 (2001). See also Johnson v. Brown & Williamson Tobacco Corporation, 122 F.Supp.2d 194, 203 (D. Mass. 2000)(implied warranty of fitness for a particular purpose based on failure to warn preempted).

Further, focusing on the required elements of a claim of breach of the implied warranty of fitness for a particular purpose, it is patent that this theory of recovery is not available to the plaintiff. It is undisputed that up to the date of her deposition, the plaintiff did not know the name of the company that manufactured Tri-Luma Cream, and she has never made a claim that she interacted with Hill Laboratories with regard to the purchase of Tri-Luma Cream. Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume II, Page 197, Lines 2-24. Accordingly, the plaintiff cannot establish that she, either expressly or by implication made known to Hill Laboratories that she intended to use Tri-Luma Cream for a particular purpose. In addition, because Ms. Haughton admittedly did not read any instructions or warnings furnished with the Tri-Luma Cream, See Exhibit 2, Transcript of the Deposition of Patricia Haughton, Volume 2, Page 70, Lines 18-22, and Page 71, Lines 17-21, she cannot point to these materials to suggest that she relied on the skill or judgment of Hill Laboratories with regard to her use

of it. See Fernandes, 400 Mass. at 34 (1987); Payne v. R.H. White Co., 314 Mass. 63, 66-67 (1943).

In sum, the plaintiff cannot meet the required elements of a claim for a breach of the implied warranty of fitness for a particular purpose; and therefore, summary judgment is appropriate as to this claim.

IV. The Plaintiff's Intentional Infliction of Emotional Distress Claim Fails

Hill Laboratories is entitled to summary judgment on Count IV of the Amended Complaint as the plaintiff cannot meet her burden to prove the elements of her intentional infliction of emotional distress claim. Under Massachusetts law, a plaintiff who alleges intentional infliction of emotional distress must prove:

> (1) that the [defendant] intended to inflict emotional distress or that he knew or should have known that emotional distress was the likely result of his conduct; (2) that the conduct was extreme and outrageous; (3) that the actions of the defendant were the cause of the plaintiff's distress; and (4) that the emotional distress sustained by the plaintiff was severe.

Haddad v. Gonzalez, 410 Mass. 855, 871 (1991). Conduct is considered to be "extreme and outrageous" when it goes beyond "all possible bounds of decency and is utterly intolerable in a civilized community". Agis v. Howard Johnson Co., 371 Mass. 140, 145 (1976). See also Mello v. Stop & Shop Companies, Inc., 402 Mass. 555 (1988)(holding evidence did not warrant a finding that the defendant's conduct was extreme and outrageous in character); Conway v. Smerling, 37 Mass. App. Ct. 1 (1994)(same). Capouto v. Boston Edison Co., 924 F.2d 11, 14 (1st Cir. 1991). The threshold required for an actionable intentional infliction of emotional distress claim is high and such claims

are often "weeded out at the summary judgment stage." Caputo v. Boston Edison Company, 924 F.2d 11 (1st Cir. 1991).

Under the circumstances of this case, summary judgment should be granted forthwith on the intentional infliction of emotional distress claim. The plaintiff has never articulated the bases for such a claim, let alone, presented any facts on which such a claim would be based. There is simply no support for such a claim.

CONCLUSION

For these reasons, Hill Laboratories, Inc. respectfully requests that summary judgment be granted in its favor as to all claims.

HILL LABORATORIES, INC.
By its Attorneys
CAMPBELL CAMPBELL EDWARD AND CONROY
PROFESSIONAL CORPORATION,

/s/ Michelle I. Schaffer

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CERTIFICATE OF SERVICE

I, Michelle I. Schaffer, certify I served a copy of the foregoing document on August 6, 2007, upon the following counsel of record by first class mail:

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/s/ Michelle I. Schaffer

Michelle I. Schaffer